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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,808	04/26/2005	Yoram Palti	P-5488-US	8892

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EXAMINER	
SINGH, SATYENDRA K	
ART UNIT	PAPER NUMBER
1657	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,808	PALTI ET AL.	
	Examiner	Art Unit	
	SATYENDRA K. SINGH	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-25 and 30-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-25 and 30-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/26/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response (and amendments to the pending claims) filed with the office on January 24th 2008 is duly acknowledged.

Claims 1-22, and 26-29 have been canceled by applicant's current amendments to the claims.

Claims 22-25 (applicant's elected invention of **Group III**) and newly added claims 30-36 are examined on their merits in this office action.

NOTE: Applicants are advised that the response filed on January 24th 2008 erroneously (presumed typographical error) refers to **an incorrect application No.** (10/486499, filed on Feb. 11, 2004) on each of the pages 2-5. Applicants are requested to use correct application number when filing response/remarks, or amendments to claims in order to avoid ambiguity in the future prosecution.

Election/Restrictions

Applicant's election of **Group III** (claims 22-25, and newly added claims 30-36, drawn to a method for *in vivo* detection of *H. pylori*) in the reply filed on January 24th 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, and did not specifically state whether the election of Group III was made with or without traverse, the instant election has been treated as an election **without traverse** (MPEP § 818.03(a)).

Claims 22-25 (as currently amended), and newly added claims 30-36 (elected invention of Group III) are examined on their merits in this office action.

Claim Suggestions

All through the claims, applicants recite the term "in vivo", which is not italicized (i.e. ***in vivo***). Applicants are requested to amend the claims

appropriately to reflect such change. Similarly, the biological name of the microbe "H. pylori" should be italicized (i.e. ***H. pylori***) in the claims (see instant claim 22, in particular) as well as in the instant disclosure, wherever possible in order to adhere to commonly used scientific practices. Appropriate correction is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 22-25 and 30-36 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are as described below: The invention of claim 22, as recited, is directed to "a method for in vivo detection of H. pylori" the method comprising:

> -inserting an autonomous in vivo sensing device into an upper gastrointestinal tract;
> -sensing pH in at least one location in the upper gastrointestinal tract using said autonomous in vivo device; and
> -transmitting pH data to an external receiving unit."

The method as recited requires the method step of "sensing pH" by said "autonomous in vivo device", however, it does not require the step of collection or acquisition of "pH data" that is required by the next method step of "transmitting pH data to an external receiving unit". Additionally, the method of claim 22, as presented, does not provide an essential method step of correlating the "pH data" to the presence or absence (i.e. detection) of said "H. pylori" as eluded in the preamble of the claim. Furthermore, there is no method step in the instant claim that provides the basis for positive or negative correlation (i.e. a measure of

comparative and/or control pH data) as it pertains to the "pH data" presumably obtained by said autonomous device and its relevance to the presence or absence of the microbe, *H. pylori*, as desired by the preamble of the claimed invention. Appropriate explanation/correction is required.

2. In addition, Claims 22-25 and 30-36 are also rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: "a patient" or "a subject" into which said "autonomous in vivo sensing device" is inserted, as the claimed invention is directed to an *in vivo* microbe detection process (see instant claim 22, first method step, in particular), as evidenced by instant claim 32, for example, that requires a patient to "ingest urea" prior to said method step of "inserting" the device as claimed. Appropriate explanation/correction is required.

3. claims 23 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 23 and 33 recite the limitation of a "**predetermined** threshold", which is confusing. Since, the term "predetermined" may mean "to determine beforehand", or "to impose a direction or tendency on beforehand", it is unclear as to how one of ordinary skill in the art would understand what exactly is encompassed by said limitation as currently presented in instant claims 23 and 33. In addition, it is also not clear as to how one of ordinary skill in the art would reach at a "predetermined threshold" value of pH, when there is no guidance as to what exact conditions (i.e. components,

determinants, or determining factors) are being considered to reach such a "predetermined threshold" in the process of *in vivo* detection of a microbial organisms, as claimed. Appropriate explanation/correction is required.

4. claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 35 recites the following:

> "The method according to claim 34, wherein causing the autonomous in vivo device to contact at least one location of a stomach mucus is by positioning a patient to achieve **substantially covering** of the patient's stomach."

The claim recitation is confusing. It is unclear as to what exactly is meant or encompassed by the limitation of "to achieve substantially covering of the patient's stomach". It is not clear how and in what terms said "covering" is provided by said method step of "positioning a patient" in order to achieve "substantially covering of the patient's stomach", as claimed. Appropriate explanation/correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names **joint inventors**. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 22-25 and 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall (US 6,228,605 B1; IDS) in view of Iddan et al (US 5,604,531; IDS).

Instant claims are generally directed to **a method for *in vivo* detection of *H. pylori*** comprising: inserting an **autonomous *in vivo* sensing device** into an upper gastrointestinal tract; sensing pH in at least one location in the upper gastrointestinal tract using said autonomous *in vivo* device; and transmitting pH data to an external receiving unit; wherein the method further comprising indicating a pH value which is about equal to or exceeds a predetermined threshold; wherein sensing pH is by imaging a color changing pH indicator; the method according to claim 23, wherein the pH value is about 5.5. The method further comprising imaging the gastrointestinal tract using said autonomous *in vivo* device, wherein the step of transmitting pH data further comprises transmitting image data; the method further comprising ingesting urea prior to inserting the autonomous *in vivo* device; the method further comprising the step of causing the autonomous *in vivo* device to contact at least one location of a stomach mucus, wherein causing the autonomous *in vivo* device to contact at least one location of a stomach mucus is by positioning a patient to achieve substantially covering of the patient's stomach; the method of claim 22, wherein **transmitting is by radio frequency**.

Marshall (IDS) discloses a method for *in vivo* detection of *H. pylori* comprising inserting an autonomous *in vivo* sensing device (an endoscope; see abstract, figure 1, and summary of the invention, columns 3-6, in particular) into an upper gastrointestinal tract; sensing pH in at least one location in the upper gastrointestinal tract using said endoscope; and transmitting pH data visually

through said endoscope to an external receiving unit (the viewer, for example); wherein the method further comprising indicating a pH value which is about equal to or exceeds a predetermined threshold; wherein sensing pH is by imaging (i.e. visual determination taken as imaging) a color changing pH indicator; the method according to claim 23, wherein the pH value is about 5.5 (see use of pH indicators such as bromothymol blue and phenol red; column columns 3-6, in particular). The method further comprising visually imaging the gastrointestinal tract using said endoscope, wherein the step of transmitting pH data further comprises transmitting image data (i.e. visual inspection/transmission through an endoscope); the method further comprising ingesting urea prior to inserting the endoscope (see column6, 3rd paragraph, in particular); the method further comprising the step of causing the endoscope to contact at least one location of a stomach mucus by positioning a patient to achieve substantial covering of the patient's stomach (see taken as inherent in the method for *in vivo* detection of *H. pylori* using an endoscope, urea and pH indicators, as explicitly disclosed by Marshall on columns 3-6, and claims, in particular; see also, the 112-second rejection above)

However, the method according to claim 22, wherein the device (used to sense and collect the pH data using pH indicators that change color above about pH 5.5) is an "**autonomous *in vivo* sensing device**" and wherein the transmitting is done **by radio frequency**, is not explicitly disclosed by the invention of Marshall.

Iddan et al (IDS) disclose an autonomous video endoscope that includes a swallowable capsule (including a camera system and an optical system for imaging an area of interest such as upper GI tract), a transmitter and a reception

system, wherein the transmitter transmits the video output of the camera system and the reception system receives the transmitted video output using radio frequency (see Iddan et al, abstract, figure 1, 3B, and 5; column 1 and 3; and summary of the invention, in particular).

Thus, given the detailed disclosure for a method for *in vivo* detection of *H. pylori* in a patient or subject as disclosed by Marshall, it would have been obvious for a person of ordinary skill in the art to modify the method of Marshall by replacing or substituting the endoscope (i.e. the device) used by Marshall with a better device (i.e. a better functional analogue) disclosed by Iddan et al that works autonomously (by incorporating suitable CCD camera and optical systems) using radio frequency to receive and transmit image signal as explicitly disclosed by the invention of Iddan et al (see Iddan et al, column 1, in particular).

A person of ordinary skill in the clinical art would have been motivated to upgrade the method of Marshall as Iddan et al disclose the potential benefits (i.e. the flexibility to move in the body cavities, option of imaging the entire digestive tract and hard to reach parts without discomfort associated with older endoscopes; see Iddan et al, column 1, Background of the invention, in particular) of using such independent devices that can be contained in a capsule, and that have all the required components to provide the capability of sensing internal pH, acquiring pH data using the color change in the form of an image data, and storing and transmitting said data using RF signals, wherein the data can be further correlated with the presence and/or absence of the microbe, H. pylori as explicitly disclosed by Marshall's invention. Such beneficial

modification, therefore, would have been clearly within the perception of an artisan of ordinary skill in the clinical art, the artisan would have had a reasonable expectation of success in using such device (in place of older endoscopes that could not function independently) as Iddan et al clearly provide use for such an autonomous video endoscope (see figure 6, and summary of the Invention, in particular).

Thus, the entire invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the clinical art at the time the claimed invention was made.

As per MPEP 2144.06, In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).

As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 22-25 and 30-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-21 of copending Application No. 10/524,553 (common inventor, same assignee). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in said co-pending application are also directed to a similar subject matter as follows:

> "A method for in vivo analysis, the method comprising the steps of: obtaining a sample from a body lumen; combining in vivo the sample with agglutinative particles; and detecting at least one optical change in the combined sample."

Since, the disclosure of co-pending application specifically states that "*the agglutinated particles may include cells, such as bacteria (e.g. H. pylori)*" (see co-pending application, page 4, paragraph [0034], in particular), the two sets of claims are clearly co-extensive in scope, and therefore, a obviousness-type double patenting rejection is required.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

NO claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SATYENDRA K. SINGH whose telephone number is (571)272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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